## Waiver or Alteration of Informed Consent

**(Taken from: *CDC Procedures for the Protection of Human Research Participants, FY2001*)**

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the participants.

2. The waiver or alteration will not adversely affect the rights and welfare of the participants.

3. The research could not practicably be carried out without the waiver or alteration.

4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

All four criteria must be met in order to alter some or all of the consent process (45 CFR 46.116(d).

**Note: It is the responsibility of the investigator to ask the IRB for a waiver of the consent process.** When requesting a waiver or alteration of consent under 45 CFR 46.116(d), **a justification *must* be provided**. The IRB will not grant a waiver without written justification; rather, a requirement to include the justification will be included in the IRB's report.

The informed consent process shall be documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative. A copy shall be given to the person signing the form. The written consent form may be read to the participant or the participant's legally authorized representative (45 CFR 46.117), but the investigator shall give the participant or the representative adequate opportunity to read it before it is signed.

A consent form should be written at a level that is understandable to the study population. For most populations, the reading level of the consent form should be at the 8th grade level. Investigators should document to the IRB the reading level of the consent form. If the reading level is written at a different level from the 8th grade, justification should be given for the use of the reading level in the consent form.

The investigator may, as an alternative, give the participant or the representative a short written consent form which documents that the elements of the informed consent were presented orally to the participant or representative. The short written consent form is signed by the participant or representative. When this method is used, a witness should observe the oral presentation and a written summary of what is to be said to the participant or representative should be used. The witness should sign the short written consent form and the summary. The person actually obtaining consent should sign the summary. A copy of the summary should be given to the participant or the representative, in addition to a copy of the short written consent form.

**Waiver of Documentation of Informed Consent**

An IRB may waive the requirement for the investigator to obtain a signed consent form (45 CFR 46.117 (c)) for some or all participants under one of two conditions:

1. The only record linking the participant and the research would be the consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.

2. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. In either case, the IRB may require the investigator to provide participants with a written statement regarding the research.

**Waiver of Parental Permission for Minor Participation in Research**

The mere existence of laws authorizing minors to consent to specific medical treatments (e.g. treatment of sexually transmitted diseases) should not be broadly interpreted to authorize minors to consent to research regarding that treatment, unless so stated in the law. This interpretation should not unduly restrict otherwise ethical research. IRBs may waive the requirement for parental permission in accordance with the procedures set forth in 46.116 or 46.408(c) if appropriate measures are taken to protect the interests of minors.

**Note**: **It is the responsibility of the investigator to ask the IRB for a waiver of informed consent, documentation of consent, or of parental permission.**

When requesting a waiver of written documentation of consent under 45 CFR 46.116, 45 CFR 46.117, or 45 CFR 46.408(c), **a justification *must* be provided**. The IRB will not grant these waivers without written justification; rather, a requirement to include the justification will be included in the IRB's report.